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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/579,222	01/09/2007	Guenter Hoelzemann	24945-0034.US	7107				
7590 09/07/2007								
Ronald J. Kamis Baker & Daniels 805 15th Street, N.W. Suite 700 Washington, DC 20005		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>JAISLE, CECILIA M</td></tr></table>			EXAMINER	JAISLE, CECILIA M		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/579,222	Applicant(s) HOELZEMANN ET AL.	
	Examiner Cecilia M. Jaisle	Art Unit 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 and 32-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED OFFICE ACTION

### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 11, drawn to compounds of Formula I, classified in class 544, subclass 279, and their compositions, classified in class 514, subclass 264.11.
- II. Claim 10, drawn to processes for preparing the compounds of Formula I, classified in class 544, subclass 279.
- III. Claims 12-30 and 32-37, drawn to pharmaceutical methods using the compounds of Group I, classified in class 514, subclass 264.11.
- IV. Claims 38 and 39, drawn to intermediates to compounds of Formula I, classified in class 544, subclass 279.

The inventions are independent or distinct for the following reasons. Inventions I – IV, respectively, are not obvious variants of each other, i.e., a reference that could be used to reject one invention could not be used to reject another invention; and the inventions as claimed are either not capable of use ~~together~~ or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the Group I compounds are distinct from the pharmaceutical methods of Group III, because the Group I compounds would be expected to have different utilities. For example, the Group I compounds would be expected to be useful in the treatment of rheumatoid arthritis (US Pat. Publ. 20070060578). The Group I compounds would be expected to be prepared according to the methods shown in US

Pat. Publ. 20070060578. The Group IV compounds would be expected to be useful for as antitumor agents (US 5817669).

In the instant case, the related inventions of Groups I – IV do not overlap in scope because the inventions of Groups I – IV have acquired separate status, as evidenced by their separate classification in the art. Although some of these Groups may have the same patent classification, they would each require a separate search in the literature. Therefore, it would impose an undue burden on the examiner to search and examine these distinct inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired separate status in the art in view of their different classification and require different fields of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

A complete reply to this requirement must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

A telephone call was made to Mr. Ronald J. Kamis on Aug. 24, 2007, to propose this restriction requirement, however the conversation did not result in an election being made. The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction and election of species requirements, the election shall be treated as without traverse.

Should applicants traverse on the ground that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product claims (Group I ) and method claims (Group III). Where applicant elects claims directed to the product, and product claims are subsequently found allowable, withdrawn method claims that depend from or otherwise require all limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected method invention must require all the limitations of an allowable product claim for that method invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined claims will be withdrawn, and the rejoined claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found

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allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy,

**applicant is advised that the method claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

### ***Conclusion***

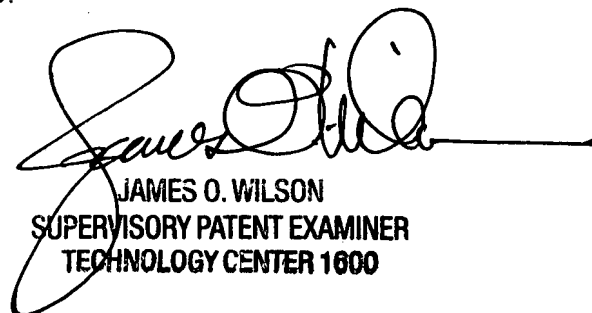
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle, J.D.

8/24/2007



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